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No. 07-525

IN THE

Supreme Court of the United States

WILLIAM J. CATALONA, *ET AL.*, PETITIONERS

v.

WASHINGTON UNIVERSITY, RESPONDENT.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

REPLY BRIEF IN SUPPORT OF CERTIORARI

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INTRODUCTION

The University's opposition to the petitions is remarkable primarily for what it does not dispute. Most significantly, the University does not dispute that the Common Rule would preempt state law if the two were in conflict, that two lower courts (including one State's highest court) have held that the Common Rule *does* preempt state law, or that this preemption issue is of substantial national importance. Instead, the University simply asserts, almost as an afterthought, that here the Common Rule and state law in fact "do not conflict." Opp'n at 25. But that assertion not only leaves unaddressed the conflict among the lower courts described in our petition, it is also untenable: The authoritative interpretation of the Common Rule forbids inducing patients to "give up *any* property rights [they] may have in * * * [their] tissue samples"—whereas the court below ruled that the University lawfully could and did induce the Patient-petitioners to give up nearly *all* of their property rights in their tissues.

Unable or unwilling to address the issue presented head-on, the University resorts instead to a series of implausible arguments against review, namely (i) that Petitioners are necessarily asking this Court to decide a question of state rather than federal law; (ii) that Petitioners failed to argue federal preemption below; (iii) that Petitioners cannot invoke the federal Common Rule to defend themselves from state-law claims because that rule provides no affirmative cause of action, (iv) that there is no conflict among the lower courts on the *federal* issue presented in the petition because some courts have agreed with the Court of Appeals' interpretation of *state* law; and (v) petitioners' position would be unwise as a matter

of policy. As we will now show, none of these arguments provides a legitimate basis for denying the petitions, which undeniably present a federal issue of national importance on which, as the University implicitly concedes, the lower courts are in disagreement.

ARGUMENT

1. In places the University's opposition suggests that petitioner is "really" seeking review of the Court of Appeals' *state law* ruling that the Patient-Petitioners made a gift of their tissues (*e.g.*, Opp'n at i, 14)—even though the question presented solely asks this Court to determine whether the Common Rule preempts state law and the entirety of his petition is directed at that issue of federal preemption, rather than the Court of Appeals' state-law holding. Obviously, the issue on which petitioner seeks review is the federal preemption issue that the Court of Appeals failed to address, and not the state-law issue on which it based its holding.

The University is equally incorrect in suggesting that a decision by this Court on the issue presented "would not change the outcome of this case," *id.* at 16, unless the Court also revisited the state-law issue decided by the Court of Appeals. The University bases this argument on the fact that the court below, in making its determination under state law, did not rely on "waiver" language specifically forbidden by federal law. *Id.* at 16-17. But that too misses the point. Dr. Catalona's petition does not argue that the exclusive problem with the University's forms was their use of the specific "waiver" language that caused the court below to find donative intent (as a matter of state law) where none existed. Rather, Dr.

Catalona seeks review of the Eighth Circuit's ruling that the *remaining* language in the University's consent forms could lawfully produce the effect proscribed by federal law—that is, transferring ownership of the Patient-Petitioners' tissues to the University. As the petition makes clear, that language renders them fatally infirm, as a matter of federal law, "*apart from* [the] specific 'waiver' clause." Pet. at 18 (emphasis added).[1]

The letter from OHRP that the University appends to its brief underscores this very point. There, OHRP notes that, "except in jurisdictions in which it has been conclusively determined that all research subjects have no legal rights in their excised biological materials, OHRP continues to find *language that waives any such legal rights* on the part of the research subjects to be exculpatory" and instructs the University to "ensure that *any such language* is removed from [its] informed consent documents." Opp'n App. at 5a (emphasis added). Further, OHRP cautions the University that specific language used in University forms several years ago—and not expressly forbidden by OHRP's interpretive guidance—was not necessarily "in compliance with the HHS * * * regulations." See *id.*

Thus, OHRP itself has now rejected the University's formalistic argument that only specific phrases identified by OHRP may violate the Common Rule. To the contrary, OHRP has now made clear that "any" language waiving subjects' "legal rights in their excised biological materials" violates that Rule. Ex-

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[1] As noted in his Petition, Dr. Catalona continues to disagree with the lower court's conclusions under state law, Pet. at 18, but does not seek review of those conclusions in this Court.

culpatory Language in Informed Consent, Office for Human Research Protections, available at: www.hhs.gov/ohrp/humansubjects/guidance/excu lp.htm. It is just such language that Dr. Catalona maintains is preempted by federal law. And that, of course, is quintessentially a federal question.

2. Contrary to the University's assertion, this question was raised in and ruled on by the District Court, and was properly raised and preserved in the Court of Appeals. The District Court, for its part, squarely held that the prohibition on inducing subjects to waive their legal rights in their tissues merely prohibited inducing patients to waive the University's negligence. Pet. App. 45a. The University ignores this ruling, Opp'n at 8, perhaps because it is directly contradicted by OHRP's recent letter stating that, "except in jurisdictions in which it has been conclusively determined that all research subjects have no legal rights in their excised biological material, OHRP continues to find language that waives any such legal rights on the part of research subjects to be exculpatory." Opp'n App. at 5a.

The University also ignores the Petitioners' express argument to the Court of Appeals that the Common Rule prohibits interpreting state law to allow transfer of ownership in human tissues. For example, Dr. Catalona's opening brief devoted several paragraphs to describing and quoting the Common Rule and invoking its "prohibition on research subjects' waivers of their legal rights." Open. Br. at 43 (attached as Appendix A). Specifically, the brief explained that the district court was "without basis" in interpreting the Common Rule's prohibition on exculpatory language to extend only to "language involving releases from malpractice or other negligence," *id.* at

43 n.10, and that the court should have recognized that the prohibition placed on the University a "legal obligation * * * not to include exculpatory language that waived any legal rights the patients may have," *ibid*; *see also id.* at 10 ("The Common Rule provides a minimum level of protection for subjects of human research, including stating what an informed consent document must contain."). Likewise, the patient-Petitioners argued that "the Common Rule's prohibition on exculpatory language, 45 C.F.R. § 46.116 bars waiver of the RPs' ownership rights in the samples provided for research." Patient Reply Br. at 20; *accord* Catalona Reply at 12 (noting that the Common Rule affords patients a "minimum set of rights").[2]

In short, both petitioners properly presented the preemption question presented here below, and the Court of Appeals simply ignored it.

3. It is also irrelevant that the Common Rule provides no private right of action. Cf. Opp'n at 20-22. After all, the Petitioners are *defendants* raising the Common Rule's preemptive effect as a bar to the Uni-

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[2] Contrary to the University's argument (at 15), the fact that petitioners did not use the word "preemption" in their briefs to the Court of Appeals is of no moment. This Court itself has often held state laws, or their application in particular cases, invalid under the Supremacy Clause without using the word "preemption" or any other magic formula. *E.g., M'Culloch* v. *Maryland,* 17 U.S. 316 (1819); *Hines* v. *Davidowitz,* 312 U.S. 52 (1941); *Hill* v. *Florida,* 325 U.S. 538 (1945); *Nash* v. *Florida Industrial Comm'n,* 389 U.S. 235 (1967). Similarly here, there can be no doubt that petitioners argued below that the district court's application of Missouri law was foreclosed by the Common Rule as a matter of federal law. And that kind of argument obviously falls under the "preemption" rubric, whether or not that label was invoked below.

versity's attempted application of state law—not plaintiffs required to state a cause of action.

Thus, as the University ultimately concedes, its real argument is that, as a matter of *policy*, "[t]his Court should not grant review of a preemption question before the agency itself has expressed a view as to whether its regulations preempt state property law." Opp'n at 21. But, again, the letter from OHRP that the University appends to its own brief makes clear that this has already happened. In that letter, OHRP instructs the University to "ensure that any [language waiving patients' property rights] is removed from informed consent documents currently used at Washington University." Opp'n App. at 5a. OHRP also warns the University that it may still "take[] * * * action" should it find the University in "noncompliance" with the Common Rule. And the University itself acknowledges that the Common Rule "govern[s] the conduct of federally funded human subject research" and authorizes OHRP to "direct[]" that certain language in its consent forms "be removed." Opp'n at 4, 17 n.4.

In short, whereas *state* law (according to the court below) would *permit* the use of exculpatory language, *federal* law, according to OHRP, requires otherwise. That is textbook conflict preemption. *Hines*, 312 U.S. at 67 (preemption occurs where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress"). And OHRP has clearly "taken a position" on that issue.[3]

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[3] OHRP's statement that, technically, "its guidance document * * * does not have a legally binding effect upon entities regulated by OHRP" is not to the contrary. Opp'n App. at 4a. Dr. Catalona does not seek to enforce the guidance document as

4. Nor does the University seriously dispute that two other courts—including the highest court of the State of Maryland—have found the Rule preemptive. Instead, the University simply notes that in those cases (*Grimes* and *Karemer-Katz*) the specific consent language at issue was different. Opp'n at 19-20. But that does not matter. The significance of those cases is that both courts held that the Common Rule preempts state law, whereas here the Eighth Circuit declined to adopt Dr. Catalona's similar argument that the Common Rule forecloses the district court's application of state law. The lower courts are thus divided on this issue.

The University counters with two state court decisions that it claims demonstrate uniformity among the lower courts on the Question Presented. See Opp'n at 19. But *Moore* and *Greenberg* were decided on *state* law grounds and did not address the preemtive effect of the Common Rule. Accordingly, it is not "telling[]" (*ibid.*) that Dr. Catalona does not cite those cases, given that they are inapposite. What *is* telling is that the University would invoke these two inapposite cases in an attempt to avoid a clear conflict among other courts.

5. Finally, the University wholly fails to rebut our showing that the lower court's decision has enormous national importance. Instead, the University argues that judicial recognition of the Common Rule's prohibition on outright donations of human tissues would overturn the status quo established by the Common Rule and would interfere with medical research.

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such, but rather the regulation that it authoritatively interprets—the Common Rule. There is no dispute that the Common Rule is itself binding on regulated entities such as the University.

Opp'n at 22-23. But OHRP's most recent letter on this question shows that the University has it backwards.

As noted, according to OHRP, "except in jurisdictions in which it has been conclusively determined that all research subjects have no legal rights in their excised human biological material, OHRP continues to find language that waives any such rights on the part of the research subjects to be exculpatory" and therefore invalid. Opp'n App. at 5a. That statement could hardly be more clear, or its application here more certain. It is undisputed that the patient-Petitioners held at least some ownership rights in their tissues under Missouri law when they agreed to allow those tissues to be used in research. That is why the lower courts attempted to determine whether the patient-Petitioners made a *donation* of those tissues by signing the University's consent forms. Pet. App. at 11a-18a, 34a-47a. According to OHRP's letter, then, "language that *waives* [those] rights * * * [is] exculpatory"—and therefore forbidden.

According to the University, this cannot be the law because Black's Law Dictionary defines "exculpatory" more narrowly. Opp'n at 22-23. But obviously it is the federal government, not the publishers of a dictionary, that provides the authoritative interpretation of the Common Rule.

Nor is there anything remarkable about OHRP's interpretation, given that the ultimate question here is one of *title*. An owner can transfer rights in property without passing title; landlords, for example, do this all the time when they sign leases. So does someone who creates a consignment—an arrange-

ment in which the consignee necessarily expects that her personal property will *not* be returned. So too here: the patients (under petitioners' view of state law as well as a proper understanding of federal preemption principles) simply allowed Dr. Catalona to perform research on their tissues without passing title. And the University has offered no sound reason why it must have title to the underlying tissues in order to obtain them and conduct research on them.

To the contrary, if the decision below stands, the risk to patients, and the corresponding risk to medical research, is grave. As shown in the petition, and not disputed by the University, the samples at issue here are important for the patients' future medical treatment, and publication of the genetic information they contain could lead to disastrous results for the patients. Pet. App. at 3a-4a. Moreover, precisely because the Common Rule provides no private right of action, the Patients are *not* fully protected by that regulation. Nor does Dr. Catalona have any assurance he will get to use the tissues; the University's Vice Chancellor for Research has told the University's Head of Urology—and admitted in sworn testimony—that he was "stalling" approval of Dr. Catalona's research. App. 2:512-13.[4]

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[4] Though its purpose in making the argument is unclear, the University declares that Dr. Catalona sent his patients a letter that violated the Common Rule by inviting them to transfer their tissues to Northwestern, and that this conclusion is "undisputed." Opp'n at 31. That is false. Dr. Catalona showed in his briefs to the Eighth Circuit that "the letter was valid under the Common Rule because it did not, and was never intended to, function as an informed consent form; before Dr. Catalona could conduct additional research on his patients' tissues, Northwestern University must obtain their consent." Catalona Reply at 25 n.8.

These uncertainties created by the decision below, moreover, severely threaten medical research. As the amicus brief of Us TOO, International explains in greater detail, patients will be disinclined to participate in medical research if they believe they will lose all control over their irreplaceable genetic information. Us TOO Int'l Br. at 9-22. And that disincentive is yet another, powerful reason for this Court to grant review and to make clear to the lower courts—and research institutions—that binding federal law prohibits that result.

CONCLUSION

The petitions should be granted.

Respectfully submitted.

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